



PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hermann et. al.

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Art Unit: 1646

Serial No.: 09/175,713

Examiner: Janet L. Andres

Filed: October 20, 1998

Entitled: Chemokines with Amino-
Terminal Modifications

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H.J.
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Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

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REPLY BRIEF PURSUANT TO 37 C.F.R. § 1.193(b)(1)

I

INTRODUCTION

This Reply Brief is being submitted in response to Examiner's Answer mailed on February 27, 2002, in the above-identified appeal. This Reply addresses some of the statements and positions taken in the Examiner's Answer, but does not comment on each and every one of them. The lack of a comment on any given statement made by the Examiner does not mean that Appellant is in agreement with the Examiner's statement. Rather it means that Appellant believes the issue has been sufficiently addressed by the earlier papers in this appeal. This Reply Brief is submitted in triplicate.

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II
ARGUMENT

1. The subject matter of claims 1-14, 17 and 18 is supported by the disclosure

Claims 1-14, 17 and 18 are rejected as lacking sufficient written description under 35 U.S.C. § 112, paragraph 1. According to the Examiner, “the claims encompass not only specific enumerated molecules, but also variants and sequences comprising them.” *See* Examiner’s Answer at p.9. In order to comply with the written description requirement, an applicant need only convey with **reasonable clarity** to those skilled in the art that, as of the filing date sought, he was in possession of the invention. Appellants have more than met the requirement for “reasonable clarity.” Appellants have provided sufficient detail in the specification in Example 1, which would enable one of ordinary skill to recognize that Appellants were in possession of the subject matter of the invention in claims 1-5, 10-14, 17 and 18. Example 1 sets forth specific details of the methods used to construct exemplary amino-terminal-modified chemokines, namely GroHEK/hSDF-1 α , GroHEK/hSDF-1 β , met-hSDF-1 α and met-hSDF-1 β . The Example illustrates how to add a specific moiety (methionine or GroHEK) to the amino-terminal end of a chemokine having a known sequence. The chemokines claimed in claims 1-5, 10-14, 17 and 18 belong to the C-C, CXC or CX3C class of chemokines (*See* Specification at p.2) and **were well known in the art by their common laboratory names long before the filing date of the instant application.** *See* references cited in Specification at p.17, lines 21-25, and p.18, lines 1-2. Similarly, modification of the N-terminus of an amino acid with an aminooxypentane residue was also well known in the art at the time of the filing of Appellant’s application. *See* Specification at p.18, lines

24-25, and p.19, lines 1-4. Therefore, coupled with information known in the art, Appellants have described a procedure of generating chemokine compositions modified at the amino-terminus and those of ordinary skill in the art would readily recognize that Appellants were in possession of the invention as **claimed**, i.e., a specifically enumerated list of chemokines having known sequences that are modified with GroHEK, methionine or aminooxypentane at the amino-terminus. In sum, given the description of the invention in the Examiner has not met her burden of presenting by a preponderance of the evidence why a person in the art would not recognize in Appellant's disclosure, a description of the invention as **defined by the claims**.

2. **The subject matter of claims 1-5, 10-14, 17 and 18 is enabled by the disclosure**

Claims 1-5, 10-14, 17 and 18 have been rejected under 35 U.S.C. § 112, paragraph 1 as not being enabled by the disclosure. Although Examiner agrees that one of ordinary skill in the art could make any particular modified chemokine, she states "the claims were rejected because the skilled artisan could not use the invention as broadly claimed." See Examiner's Answer at p.12. Examples 2-6 in the Specification provide protocols for the various uses of the amino-terminal-modified chemokines of the instant invention. Under *In re Wands*, if there is considerable direction and guidance in the specification, if there is a high level of skill in the art at the time the application was filed, and if all of the methods needed to practice the invention are either disclosed in the specification or are well known, then the specification is enabling with respect to the claims at issue. All of the *In re Wands* considerations are applicable in the instant case, i.e., there is considerable guidance in the specification,

there was high level of skill in the art at the time the application was filed and all of the methods needed to practice the claimed invention are either disclosed or well known in the art. Appellants have provided details in the specification and in the form of working examples to enable one of ordinary skill in the art to practice the claimed invention. In addition, as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. In the instant case, Appellants have disclosed several working examples to illustrate the various uses of the invention. In the instant case, Appellants have provided a detailed road map to enable one of ordinary skill in the art to practice the invention without undue experimentation. Appellants therefore submit that the “use” aspect of the claimed invention has met.

III **CONCLUSION**

In view of the foregoing, Appellants respectfully submit that claims 1-14, 17 and 18 on appeal are allowable. Favorable action and approval of the application for allowance are respectfully requested.

The Commissioner is hereby authorized to charge Deposit Account No. 10-0447, reference 50657-05302USP1 for any additional fees inadvertently omitted, which may be necessary now or during the pendency of this application, except for the issue fee.

In accordance with 37 C.F.R. § 1.192(a), this brief is submitted in triplicate.

Respectfully submitted,

Date: April 29, 2002

By:



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